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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,316	02/09/2004	Yasuhiro Matsumura	1021.43503X00	1058
20457	7590	11/02/2006	EXAMINER	
ANTONELLI, TERRY, STOUT & KRAUS, LLP 1300 NORTH SEVENTEENTH STREET SUITE 1800 ARLINGTON, VA 22209-3873				HUMPHREY, DAVID HAROLD
ART UNIT		PAPER NUMBER		
		1643		

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/773,316	MATSUMURA ET AL.
	Examiner	Art Unit
	David Humphrey	1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 28 September 2006.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 1-15 is/are pending in the application.  
 4a) Of the above claim(s) 1-9 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 10-15 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date 02/09/2004.

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Applicants' election of Group II (claims 10-15), without traverse in the reply filed on September 28, 2006 is acknowledged.

2. Claims 1-15 are pending.

Claims 1-9 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 10-15 are examined on the merits.

***Specification***

3. Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 11 and 12 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 11 is vague and indefinite for the recitation of "said container storing said solid carrier... is connected to said filter portion." It is unclear whether the solid carrier or the container is united or joined with the filter. In addition, it is unclear *how* the solid carrier or container is joined with the filter portion. One of ordinary skill in the art would be unable to determine the metes and bounds of the claimed invention.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. §102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 10-15 are rejected under 35 U.S.C. §102(e) as being anticipated by Obiso et al. (U.S. Patent Publication 2003/0059839; filed 05/21/2002).

Obiso et al. disclose a cell recovery apparatus containing one or more containers with a solid carrier, such as magnetic beads, and buffer solutions, see page 2, paragraph 17, lines 1-7; page 3, paragraph 44, lines 1-4; page 9, paragraph 146, lines 1, 2, 9, and 10; page 9, paragraph 157, lines 1-7. The instant specification contains no definition for the term "bag". Merriam-Webster's Collegiate Dictionary, 10<sup>th</sup> edition, defines "bag" as "a flexible container that may be closed for holding, storing, or carrying something", see page 86, left column. The broadest reasonable interpretation of "bag" reads on one of the disclosed containers. Therefore, since Obiso et al. disclose one or more containers, the reference reads on the instant recovery apparatus containing a bag and a container. The container provides an agitating means to agitate the sample (see page 6, paragraph 103) and filtering the sample with one or more filters, see page 6, paragraph 105. Absent evidence to the contrary, Obiso et al. disclose that the filter is connected to the bag and the container is connected to the filter. Obiso et al. disclose that the samples may or may not be heat inactivated, thereby providing no temperature control means, see page 12, paragraph 174, lines 9-11; page 5, paragraphs 67 and 83, lines 1 and 2.

8. Claims 10, and 13-15, are rejected under 35 U.S.C. §102(b) as being anticipated by Roche et al. (U.S. Patent 5,891,651, issued 04/06/1999).

Roche et al. disclose an apparatus for isolating cells from a stool sample containing a bag and packaging material, see column 3, lines 22-31; column 8, lines 48-53. The packaging material of the patent is regarded by the Examiner as a container

comprising a reagent, magnetic beads. The magnetic beads are a solid carrier whereby isolated cells are separated from the sample magnetically, see column 2, lines 59-63; column 6, lines 55-63. Roche et al. disclose a bag wherein the sample is agitated, see column 8, lines 49-51. The said disclosed apparatus had no temperature control means, see for example, column 9, lines 59 and 60.

9. Claims 10, and 13-15, are rejected under 35 U.S.C. §102(e) as being anticipated by Roche et al. (U.S. Patent 5,891,651, filed 03/29/2006).

Roche et al. disclose an apparatus for isolating cells from a stool sample containing a bag and packaging material, see column 3, lines 22-31; column 8, lines 48-53. The packaging material of the patent is regarded by the Examiner as a container comprising a reagent, magnetic beads, because as defined in the claims the container contains the solid carrier, magnetic beads. The magnetic beads are a solid carrier whereby isolated cells are separated from the sample magnetically, see column 2, lines 59-63; column 6, lines 55-63. Roche et al. disclose a bag wherein the sample is agitated, see column 8, lines 49-51. The said disclosed apparatus had no temperature control means, see for example, column 9, lines 59 and 60.

10. Claims 10, and 13-15, are rejected under 35 U.S.C. §102(e) as being anticipated by Nair (U.S. Patent 6,534,280; filed 03/30/2000).

Nair discloses an apparatus for recovering cells from a stool sample at ambient temperature comprising a Stomacher bag and vials and tubes. In the instant case, the vial or tube is regarded as a container, since Merriam-Webster's Collegiate Dictionary, 10<sup>th</sup> edition, defines "container" as "a receptacle (as a box or jar) for holding goods", see page 249, right column. The broadest reasonable interpretation of "container" includes vials and tubes. Therefore, since Nair discloses one or more vials and tubes, the reference reads on the instant recovery apparatus that includes a container.

The vial contains a solid carrier, magnetic beads, see column 2, lines 60-63; column 4, lines 55-59; column 5, lines 27 and 28; column 6, lines 43-47; column 7, lines 60-63. Nair further discloses a means for agitating the sample with the magnetic beads (see column 4, lines 59-61) and isolating the cells from the sample by magnetic means, see column 6, lines 47-51. The said disclosed apparatus had no temperature control means, see Abstract, lines 1-3.

***Claim Rejections - 35 USC § 103***

11. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 10-15 are rejected under 35 U.S.C. §103(a) as being unpatentable over Roche et al. (U.S. Patent 5,891,651, filed 03/29/1996) in view of Trudil et al. (US Patent 6,176,836, issued 01/23/2001).

The teachings of Roche et al. are described *supra*.

Roche et al. do not teach the cell recovery apparatus including one or more filter portions, wherein the filter portion is connected to the bag and the filter portion is

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connected to the container. These deficiencies are made up for by the teachings of Trudil et al.

Trudil et al. teach a biological sample collection kit wherein the filter is attached directly to the collection bag and the collection tubes are in one package, see column 2, lines 16-20.

It would have been *prima facie* obvious for one of ordinary skill in the art to modify the collection bag of Roche et al. to include the filter as taught by Trudil et al. One of ordinary skill in the art would have been motivated with a reasonable expectation of success to implement the teachings Trudil et al. in the method of Roche because Trudil et al. teach that filters serve the purpose of keeping out large, extraneous material and an apparatus having all the materials in one package limits the risk of contamination of the sample and erroneous results, see column 1, lines 18-21; column 2, lines 36-40. This results in a cell recovery apparatus for isolating cells from a stool sample that is more efficient, see Trudil et al. column 1, lines 21-24.

13. Claims 10-15 are rejected under 35 U.S.C. §103(a) as being anticipated by Nair (U.S. Patent 6,534,280; filed 03/30/2000) in view of Trudil et al. (US Patent 6,176,836, issued 01/23/2001).

The teachings of Nair are described above.

Nair does not teach the cell recovery apparatus including one or more filter portions, wherein the filter portion is connected to the bag and the filter portion is

connected to the container. These deficiencies are made up for by the teachings of Trudil et al.

Trudil et al. teach a biological sample collection kit wherein the filter is attached directly to the collection bag and the collection tubes are in one package, see column 2, lines 16-20.

It would have been *prima facie* obvious for one of ordinary skill in the art to modify the collection bag of Nair to include the filter as taught by Trudil et al. One of ordinary skill in the art would have been motivated with a reasonable expectation of success to implement the teachings Trudil et al. in the method of Nair because Trudil et al. teach that filters serve the purpose of keeping out large, extraneous material and an apparatus having all the materials in one package limits the risk of contamination of the sample and erroneous results, see column 1, lines 18-21; column 2, lines 36-40. This results in a cell recovery apparatus for isolating cells from a stool sample that is more efficient, see Trudil et al. column 1, lines 21-24.

### ***Conclusion***

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Humphrey whose telephone number is (571) 272-5544. The examiner can normally be reached on Mon-Fri 8:30AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

**ALANA M. HARRIS, PH.D.  
PRIMARY EXAMINER**

*Am Harris*  
David Humphrey, Ph.D.

October 24, 2006